GAMBRO Renal Products

510K(k) SUMMARY

FEB 15 2007

SUBMITTER: **Gambro Renal Products**
10810 West Collins Avenue
Lakewood, CO 80215
(303) 231-5075

DATE PREPARED: **October 16th 2006**

DEVICE NAME: **Prisma M10 Pre Set**

CLASSIFICATION NAMES: **High Permeability Hemodialysis System**

PREDICATE DEVICES: **PRISMA M60 Set & Gambro FH 22H**

Device Description:

The PRISMA M10 Pre Set is a disposable, extracorporeal circuit for use with the PRISMA control unit. The PRISMA M10 Pre Set consists of a AN 69 hollow fiber hemofilter / dialyzer and tubing lines.

The filter is permanently connected:

- on the blood compartment to an access line (red-striped), a return line (blue-striped)
- on the dialysate compartment to a dialysate inlet line (green-striped) and to an effluent outlet line (yellow-striped).

Other lines of the set include a replacement solution line (purple-striped) and anticoagulant line.

- A 1-liter bag is connected to the end of the blood access line to collect the priming liquid.
- A 5-liter bag is connected to the end of the effluent outlet line to collect the ultrafiltrate and/or dialysate.

Pre-dilution: the PRISMA M10 Pre Set is a set provided for addition of replacement solution before blood enters the filter.

Predicate Device:

Prisma M60 Set and Gambro FH 22H

Intended Use:

The PRISMA M10 Pre Set is indicated for use with the PRISMA control unit only in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

The set is intended for use in the following veno-venous therapies:

- slow continuous ultrafiltration (SCUF)
- continuous veno-venous hemofiltration (CVVH)
- continuous veno-venous hemodialysis (CVVHD)

- continuous veno-venous hemodiafiltration (CVVHDF)

The PRISMA M10 Pre Set is intended for treatment of neonates and infants with a body weight ranging between 2 and 15 kg.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent to the predicate devices.

Summary of Non-Clinical & Clinical Tests:

In vitro performance and clinical testing was performed to establish and compare performance characteristics to the predicate devices. The results of in vitro and clinical testing demonstrate that the proposed device is substantially equivalent to the predicate devices and is suitable for the intended use.

Conclusions:

Testing performed on the Gambro Prisma M10 Pre Set indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro performance data / specifications are included in the labeling.

October 16th, 2006
Dr. Jeffrey R. Shideman
Director, Clinical Research
Gambro Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Gambro Renal Products, Inc.
c/o Jeffrey R. Shideman, Ph.D.
Director, Clinical Research
Therapy Group Americas
7307 Glouchester Drive
EDINA MN 55435

FEB 15 2007

Re: K063183
Trade/Device Name: PRISMA M10 Pre Set
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: January 17, 2007
Received: January 19, 2007

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GAMBRO Renal Products

INDICATIONS FOR USE

510(k) Number (if known): K063183

Device Name: Gambro Prisma M10 Pre Set

Indications for Use:

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Prescription Use ✓ AND/~~OR~~ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063183